REF | 9770000

BARD

ACCESS SYSTEMS

SITE RITE 6

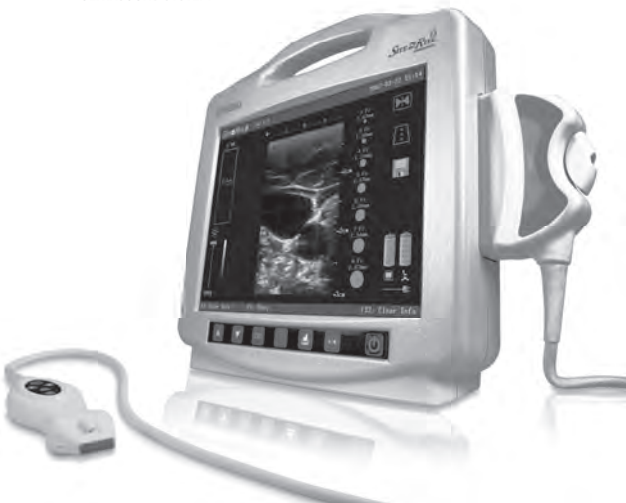
ULTRASOUND SYSTEM

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

SITE RITE 6*

ULTRASOUND SYSTEM

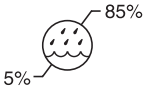


Do not operate in the presence of flammable anesthetics

BF Type Equipment

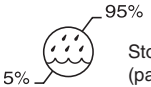
Dangerous Voltage

Attention, see instructions for use



Operating Humidity Parameters
Storage Humidity Parameters
(unpackaged)

Medical Electrical Equipment Classified by ETL with respect to Electric Shock, Fire, and Mechanical Hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1



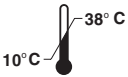
Storage Humidity Parameters
(packaged)

Rx Only

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

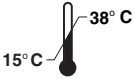
Keep Dry

Fragile



Storage Temperature Parameters

Ultrasound Probe



Operating Temperature Parameters

Do not dispose with ordinary municipal waste

Direct Current

Federal Communications Commission

Manufacturer

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Section

1 Overview

This manual provides instructions for the proper use of the Site~Rite* 6 Ultrasound System. Clinicians must have ultrasound training prior to operating this system. For additional information or product training, contact your local Bard Access Systems sales representative.

1.1 Indications For Use

The Site~Rite* 6 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.

1.2 Site~Rite* 6 Ultrasound System and Components

The Site~Rite* 6 Ultrasound System is an easy to use and portable ultrasound scanner.

Site~Rite* 6 Ultrasound System and Authorized Accessories include:

- Site~Rite* 6 Ultrasound System scanner
- Site~Rite* 6 Ultrasound System vascular access probe
- Site~Rite* 6 Ultrasound System roll stand
- Site~Rite* 6 Ultrasound System printer
- Site~Rite* 6 Ultrasound System base power unit
- Site~Rite* 6 Ultrasound System A/C adapter
- Site~Rite* 6 Ultrasound System line cord
- Site~Rite* needle guides
- Site~Rite* probe covers
- Ultrasound gel
- Ultrasound vessel phantom
- USB storage device with no external power connection (e.g. USB flash drive)

Contact your Bard Access Systems' Sales Representative or Customer Service at (800) 545-0890 to order.

1.3 Warnings, Precautions and Notes

Warnings

Warning: This product should only be operated by qualified medical personnel.

Warning: Do not remove outer protective covers from the Site~Rite* 6 Ultrasound System scanner. Hazardous voltages exist at several points within the system.

Warning: Do not operate the Site~Rite* 6 Ultrasound System or the Site~Rite* 6 Ultrasound System power sources in the presence of flammable anesthetics or gases. Explosion may result.

Warning: Do not use for ophthalmic indications. Ophthalmic use may cause patient injury.

Warning: Misuse of the Site~Rite* 6 Ultrasound System may result in damage to the equipment or personal injury.

Warning: Use only the Site~Rite* 6 Ultrasound System A/C adapter to charge the Site~Rite* 6 Ultrasound System. Use of any other device to charge the Site~Rite* 6 Ultrasound System may damage the battery packs, may cause intermittent or unpredictable operation, may damage the system, may result in injury and will void your warranty.

Warning: If a probe is damaged in any way, discontinue use immediately. Damage to the scanner may occur.

Warning: Avoid subjecting the probe to excessive mechanical shock. Damage to the probe may occur.

Warning: Use only Bard Access Systems probes with this system. Use of unapproved probes may result in patient injury or equipment damage.

Warning: When using Site~Rite* Needle Guides on the Site~Rite* 6 Ultrasound System probe, use only sterile plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Warning: Do not allow liquid to enter the scanner, A/C adapter, base power unit, probe connector or probe port. Damage to the equipment may occur.

Warnings (continued)

Warning: Do not attempt to sterilize the Site~Rite* 6 Ultrasound System scanner or probe with ethylene oxide or heat sterilization methods. Damage to the equipment may occur.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite* 6 Ultrasound System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.

Warning: The following actions void the warranty of the Site~Rite* 6 Ultrasound System and may result in injury or equipment damage:

- Opening or servicing the scanner or the probe housing by anyone other than Bard Access Systems authorized service personnel.
- Removal of system labels by anyone other than Bard Access Systems authorized service personnel.
- Opening or servicing the base power unit or the A/C adapter by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite* 6 Ultrasound System scanner to any power source other than the Site~Rite* 6 Ultrasound System A/C adapter and/or base power unit.
- Connecting the Site~Rite* 6 Ultrasound System to any unauthorized accessory. Refer to Section 1.2.

Warning: Inspect power cords for damage. If any of the prongs are damaged, use battery power until a replacement cord is obtained.

Warning: Verify that all accessories attached to the system comply to 60601 safety standards. Non-compliance may result in increased patient risk.

Warning: Use only IEC or ISO approved safety devices outside the patient environment. Failure to do so may damage the equipment.

Warning: Equipment that only relies on basic insulation should not be used with this system. Failure to comply could result in increased patient risk.

Warnings (continued)

Warning: Maximum shelf load on the VAD bedside roll stand is 22 lbs. Exceeding this weight may damage the roll stand.

Warning: Do not overtighten screws when attaching the scanner to the roll stand mount. Doing so may damage the scanner.

Warning: Use only screws provided in the packaging. Ensure the unit is secure against the roll stand mount. Failure to do so may cause the scanner to disconnect from the roll stand.

Warning: Do not use the probe with high frequency surgical equipment. Doing so may damage the equipment.

Warning: Do not pull on the probe cable or overload the roll stand. Doing so may cause the system to tip.

Warning: The keyboard tray and arm are designed to support the keyboard weight only. Additional weight may cause the stand to tip.

Precautions

Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If, however, a certain threshold has been passed, biological effects may occur. While the Site~Rite* 6 Ultrasound System acoustic output parameters fall well below all FDA thresholds for adverse biological effects, any given ultrasound procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Caution: Do not pull the cable to disconnect the probe connector from the scanner. Pulling the cable may damage the cable, cable connection or scanner.

Caution: Do not twist or bend the probe cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure, intermittent or unpredictable operation.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak the probe cable, cable bend relief, probe connector or probe buttons. Doing so may damage the probe.

Caution: Inspect the keyboard prior to each use. If damage is noted, do not use the keyboard.

Caution: Only apply commercially available ultrasonic couplant, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe.

Caution: Use water or rubbing alcohol and a soft cloth to remove couplant from the acoustic window (or face) of the probe. Failure to do so may scratch the acoustic window.

Caution: Do not to allow ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry couplant from the acoustic window (or face) of the probe.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: “Medical Alert: Allergic Reactions to Latex-Containing Medical Devices”, issued March 29, 1991.
Bard Access Systems distributes sterile probe covers and needle guide kits that do not contain latex.

Caution: Do not force the probe connector. Damage to the connector and system could result.

Caution: Always snap the needle guides on to the probe hook. Do not slide the needle guide on to the needle guide hook, as the sterile sheath may tear.

Caution: Do not subject the probe to excessive vibration. Vibration may dislodge sensitive components and cause intermittent or unpredictable operation.

Caution: Prior to each use, inspect the integrity of all power cords and connectors as well as the integrity of the unit itself. If any problems are found, discontinue use immediately and contact an authorized service representative. Use of a damaged power cord could damage the machine.

Caution: During use, the A/C connector needs to be easily accessible. In case of emergency remove the power cord as soon as possible.

Caution: To avoid unnecessary strain, use the device in a comfortable manner.

Precautions (continued)

Caution: Attach the power source in such a way as to prevent damage. Improper installation may damage power cords.

Caution: Inspect the probe prior to each use. If damage to the cable or transducer face is noted, do not use the probe. Damage to the system may occur.

Caution: Hot water (in excess of 113° F or 45° C) may damage the probe.

Caution: Use only Bard Access Systems cleaning and disinfection procedures. Failure to do so may damage the device.

Notes

Note: When cleaning the system and components, it is important to remove all particles or other matter from all surfaces and crevices.

Note: For 240 V applications use only center tapped 240 VAC single phase power.

2 Assembling the Site~Rite* 6 Ultrasound System

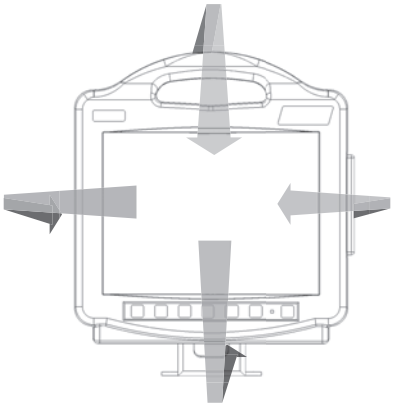
Unpack the Site~Rite* 6 Ultrasound System and verify the contents against the packing slip. Inspect all parts for damage. If any damage is found, please contact Bard Access Systems at 800-443-3385.

2.1 Assembling the Roll Stand

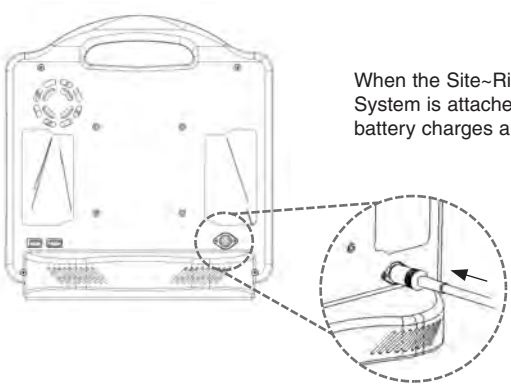
Refer to roll stand assembly instructions.

2.2 Adjusting the Scanner on the Roll Stand

Tilt and Swivel Adjustment



2.3 Attaching the Power Source and Charging the Battery



When the Site~Rite* 6 Ultrasound System is attached to A/C power, the battery charges automatically.

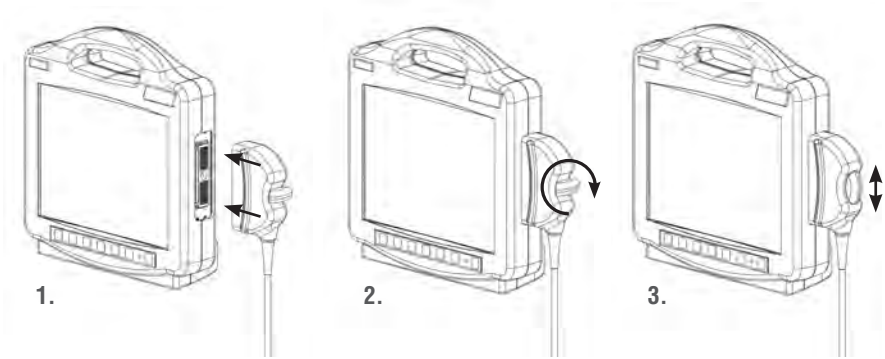
Warning: Use only the Site-Rite* 6 Ultrasound System A/C adapter to charge the Site-Rite* 6 Ultrasound System. Use of any other device to charge Site-Rite* 6 Ultrasound System may damage the battery packs, may cause intermittent or unpredictable operation, may damage the system, may result in injury and will void your warranty.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

Warning: Inspect power cords for damage. If any of the prongs are damaged, use battery power until a replacement cord is obtained.

Caution: Attach power source in such a way as to prevent damage. Improper installation may damage power cords.

2.4 Connecting and Disconnecting the Site~Rite* 6 Ultrasound System Probe



Warning: Use only Bard Access Systems probes with this system. Use of unapproved probes may result in patient injury or equipment damage.

Caution: Do not pull the cable to disconnect the probe connector from the scanner. Pulling the cable may damage the cable, cable connection or scanner.

Caution: Do not twist or bend the probe cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure, intermittent or unpredictable operation.

2.5 Powering on the Site~Rite* 6 Ultrasound System

To power on the Site~Rite* 6 Ultrasound System

1. Verify that the probe is connected to the Site~Rite* 6 Ultrasound System scanner.
2. Depress and release the power button located on the front of the Site-Rite* 6 Ultrasound System scanner.
3. Wait approximately 20 seconds for the display screen to illuminate.
4. To power off the Site~Rite* 6 Ultrasound System, depress and release the power button again. The system is powered off when the display screen darkens.

2.6 Resetting the Site~Rite* 6 Ultrasound System

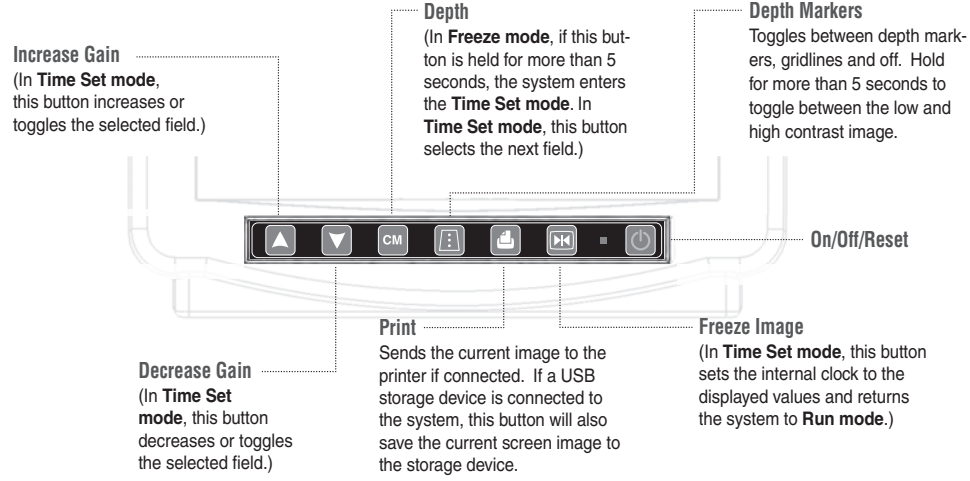
Should the scanner display ever appear blank or show an exclamation mark (**!**), the system may need to be reset.

To reset the system:

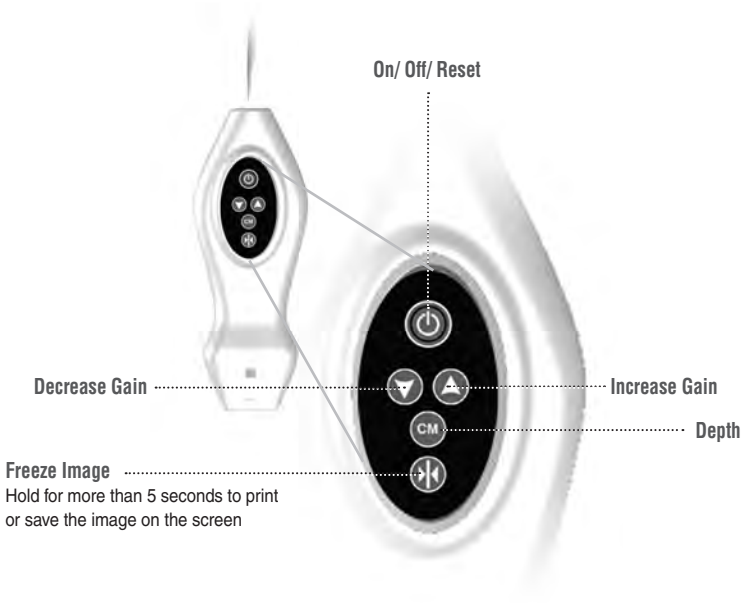
1. Depress and release the power button located on the front of the Site~Rite* 6 Ultrasound System scanner.
2. Wait approximately 60 seconds for the unit to reset itself.
3. Power the unit back on per instructions in section 2.5.

3 Site~Rite* 6 Ultrasound System Information

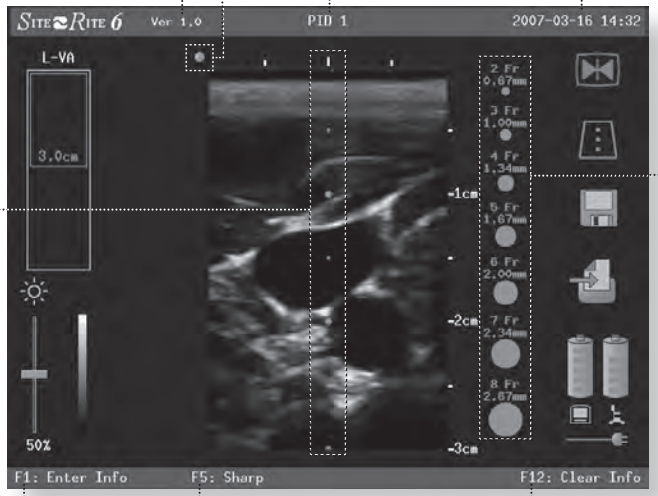
3.1 Front Panel Controls



3.2 Probe Controls



3.3 Display Screen Information



Display Screen Information

Probe Depth Indicator
Indicates current image depth

6.0 cm
4.5 cm
3.0 cm
1.5 cm

A/C Power Indicator

Not Connected to A/C Wall Power
Connected to A/C Wall Power

Printer Indicator

Printer Error
Printing in Progress
No Printer Connected
Printer Connected

Contrast Indicator

High Contrast Image
Low Contrast Image

Battery Requires Calibration

Battery Indicator

There are 5 charge levels on each battery indicator. When the unit is recharging, the indicator is green for all 5 levels. When the unit is operating on battery power, the scanner battery indicator changes to yellow at 40% and red/blinking at 20% of the remaining battery life.

Battery Malfunction
Cart Battery Not Connected
Cart Battery Indicator
Scanner Battery Indicator

Depth Marker Indicator

Depth Markers/ Gridlines Off
Depth Markers/ Gridlines On

Gain Indicator

Adjustable Gain Level (0-100%)

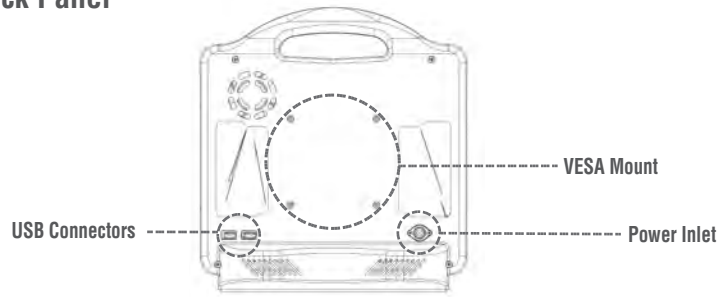
Storage Device Indicator

No Storage Device Connected
Storage Device Error
Storage Device Full
Writing to Storage Device
Storage Device Connected

Run/Freeze Indicator

Run Mode
Image Freeze Mode (blinking)

3.4 Back Panel

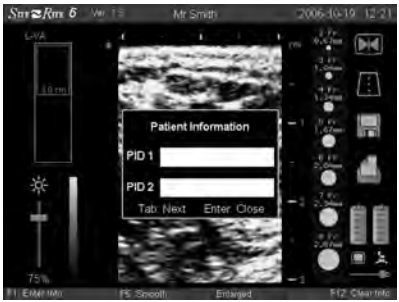


3.5 Entering Patient Information

Patient identification (PID) information can be entered for each ultrasound image. PID information could include patient name, patient chart number, or other identification information.
To enter PID information:

1. Press **F1** on the keyboard to display the Patient Information window shown in the figure.
2. Enter PID information in the PID 1 and PID 2 fields by using the keyboard. A maximum of seventeen characters can be entered in each PID field, including A-Z, a-z, 0-9 and "space".
3. To toggle between the PID 1 and PID 2 fields, press the tab key.
4. To close the Patient Information window, press the enter key.

   Note: The information in the PID 1 field will be displayed in the title bar above the image.
5. To clear PID information, press the F12 key.



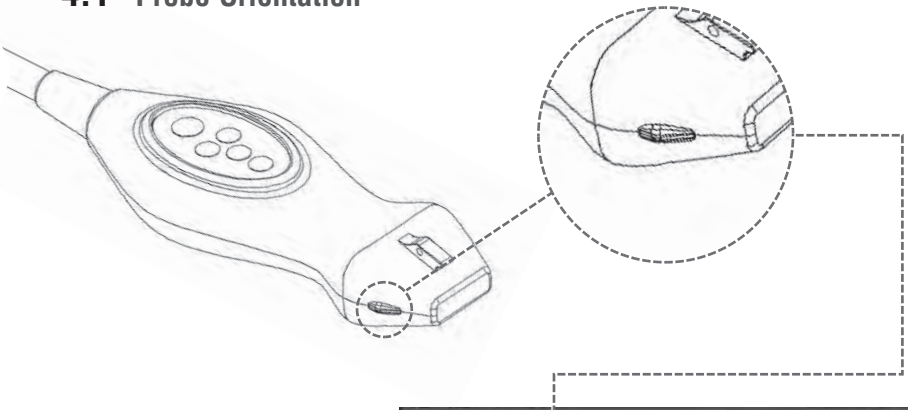
Note: The patient information will be lost when the system is powered off. To avoid information loss, save or print the image before powering off the system.

Note: When the image is saved or printed, both PID 1 and PID 2 will appear on the image copy.

Note: When saving an image to a USB flash drive, the file name will appear as follows: **PID1-Date-Time.jpg**

4 Using the Site~Rite* 6 Ultrasound System Probe

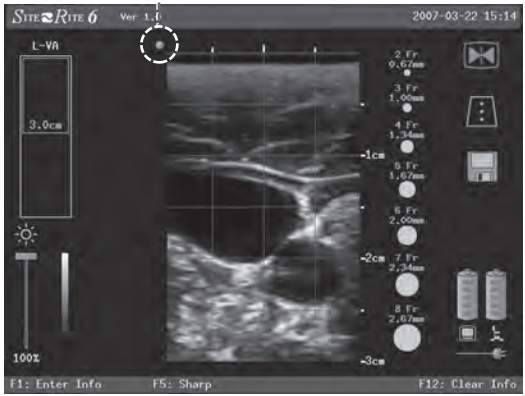
4.1 Probe Orientation



The Site~Rite* 6 Ultrasound System vascular access probe includes an orientation bump on the left side of the probe. This bump corresponds to the probe orientation mark located on the Site~Rite* 6 Ultrasound System display screen.

When using the Site~Rite* 6 Ultrasound System probe, hold the probe so that the side with the needle guide hook points away from the heart.

Warning: If the probe is damaged in any way, discontinue use immediately. Damage to the scanner may occur.



4.2 Draping the Probe for Sterile Use

When using the Site~Rite* 6 Ultrasound System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.

Warning: Use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices", issued March 29, 1991. Bard Access Systems distributes sterile probe covers and needle guide kits that do not contain latex.

To purchase sterile plastic probe covers, contact Bard Access Systems' Customer Service at:

Customer Service: (800) 545-0890
www.bardaccess.com

To drape the probe for sterile use:

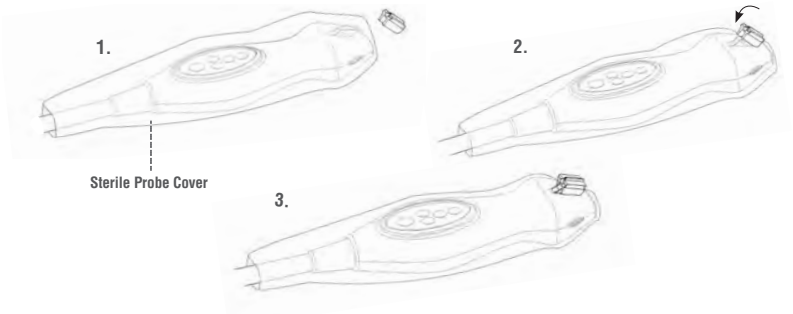
1. Place the probe in the side arm probe holder on the roll stand.
2. Apply a layer of non-sterile ultrasonic coupling gel on the acoustic window of the probe head.
3. Make sure that the probe cover is fully rolled up.
4. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
5. Cover the probe and cable with the probe cover.
6. Smooth the probe cover over the acoustic window of the probe head to remove any air bubbles or folds in the sheath.
7. Use the latex free poly-bands to hold the probe cover in place.
8. Apply a layer of sterile coupling gel to the covered acoustic window.

4.3 Ultrasound Guidance for Vascular Access

To use the Site~Rite* 6 Ultrasound System for vascular access:

1. Drape the probe for sterile use. Refer to instructions in Section 4.2.
2. Attach a needle guide to the probe.

Caution: Always snap needle guides onto the probe hook. Do not slide the needle guide on to the guide hook, as the sterile sheath may tear.



3. Slide the appropriately sized needle, beveled edge facing the probe, into the channel on the guide.
4. Place the probe against the skin, perpendicular to the target vessel.
5. Hold the probe so that the side with the needle guide hook points away from the heart.
6. Center the dot markers on the target vessel.
7. While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the screen of the Site~Rite* 6 Ultrasound System scanner. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.
8. Hold the needle, then gently rock the probe away from the needle for a smooth separation. The needle guide channel opens, and the needle smoothly disengages from the guide.

To purchase Needle Guides and sterile plastic Probe Covers, contact Bard Access Systems' Customer Service at:
Customer Service: (800) 545-0890 www.bardaccess.com

For instructions on the proper use of the Site~Rite* Needle Guides, refer to the Site~Rite* Needle Guide Kits & Ultrasound Probe Cover Kits Instructions for Use.

Warning: When using Site~Rite* Needle Guides on the Site~Rite* 6 Ultrasound System probe, use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

5 Settings

5.1 Date, Time and Image Size

To modify date, time and image size settings:

1. Press the Freeze button (▶|◀) to pause the system.
2. Press and hold the Depth button (**cm**) for more than 5 seconds to enter the time/image size mode. The year field will then be highlighted. Release the Depth button.
3. Press the Depth button (**cm**) to select the desired date or time field to be modified.
4. Press the Gain buttons (▲, ▼) to change the selected date or time values.
5. After setting the date and time, press the Depth button (**cm**) to enter the image size field. The current image size will be highlighted.
6. Press the Gain buttons (▲, ▼) to select the desired image size.
7. Press the Freeze button (▶|◀) to store the updated settings and resume normal operation.

5.2 Image Parameters

The Site~Rite* 6 Ultrasound System image may be changed from the factory default settings.

Contrast

- Press and hold the Depth Marker button (/:\) for 5 seconds to toggle between the high and low contrast image.

Smooth/Sharp

- Press the F5 key to toggle between a smooth and sharp image.

5.3 Sizing Tools

Gridlines can be viewed over the ultrasound image to provide an effective tool to estimate vessel diameter.

- Press the Depth Marker button (/:\) to toggle the image gridlines on and off.

Catheter size icons are displayed in proportion to the vessel image at a selected depth. These icons assist clinicians in determining the appropriate catheter size for the vessel being imaged.

- Press the F9 key to toggle the catheter size chart on and off.

5.4 Image Depth

The Site~Rite* 6 Ultrasound System image depth may be changed to image structures at different depths. Adjusting the depth also adjusts the focus of the ultrasound. Adjusting the depth to place the structure of interest at the appropriate focus will improve the ultrasound image.

Image Depth Setting	Focal Depth
1.5 cm	0.6 cm
3.0 cm	1.5 cm
4.5 cm	3.0 cm
6.0 cm	5.0 cm

- Press the Depth button (**cm**) to select the image depth with the focal depth closest to that of the target structure.

5.5 Image Gain

The image gain can be adjusted to amplify the signal returned to the ultrasound scanner.

Adjusting the gain effects the entire image. Increasing gain will amplify the signal from the target structure along with non-targeted structures.

- Press the Gain buttons (▲,▼) to select the gain that provides the best ultrasound image for the targeted structure.

6 Cleaning and Disinfection

6.1 Cleaning Procedures

To clean the keyboard, scanner, probe and A/C adapter:

1. Turn off the system.
2. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
3. Gently wipe the dampened cloth over exterior surfaces requiring cleaning.

Note: When cleaning the system and components, it is important to remove all particles or other matter from all surfaces and crevices.

6.2 Disinfection Procedures

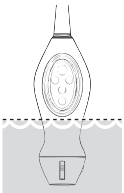
The Site~Rite* 6 Ultrasound System probe may be liquid disinfected by soaking it in Cidex* Plus 28 day solution.

Follow the solution manufacturer's recommendations for soak time necessary to achieve the desired germicide level of activity.

Warning: Do not allow liquid to enter the scanner, A/C adapter, base power unit, probe connector or probe port. Damage to the equipment may occur.

Warning: Do not attempt to sterilize the Site~Rite* 6 Ultrasound System scanner or probe with ethylene oxide or heat sterilization methods. Damage to the equipment may occur.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak the probe cable, cable bend relief, probe connector or probe buttons. Doing so may damage the probe.



Caution: Hot water (in excess of 113°F or 45°C) may damage the probe.

Caution: Use only Bard Access Systems cleaning and disinfection procedures. Failure to do so may damage the device.

For a list of disinfectants recommended for use on the Site~Rite* 6 Ultrasound System and probe, contact Bard Access Systems for the "Site~Rite* Ultrasound System Compatible Disinfectants" document.

7 Troubleshooting & Error Screens

Missing/ Invalid Probe

Cause: Scanner does not recognize or identify a probe or probe not attached.
Solution: Ensure that a Site-Rite* 6 Ultrasound System probe is properly connected to the system.

System Malfunction

Cause: Scanner is not operating within normal parameters.
Solution: Discontinue use immediately. Return to authorized repair facility.

Display Malfunction

Cause: Display malfunction.
Solution: Most display malfunctions can easily be corrected by resetting the system. To do so, power off the device, wait 60 seconds, then power the system back on. If the display malfunction is not resolved by resetting the system, discontinue use and return to authorized repair facility.

Battery Empty

Cause: Battery empty.
Solution: Connect system to A/C outlet for operation and battery recharge.

Battery Malfunction

Cause: Battery malfunction.
Solution: Send system to authorized repair facility for battery replacement.

Storage Device Error

Cause: Storage device error.
Solution: Replace storage device.

Printer Error

Cause: Printer error.
Solution: Check paper or refer to printer instructions for use.

Poor Image Quality

Cause: Incorrect settings.
Solution: Refer to Section 5.

Cause: Scanner is not operating within normal parameters.
Solution: Return to authorized repair facility.

8 Upgrading Software

The Site~Rite* 6 Ultrasound System allows the software to be upgraded through the USB connectors located on the rear of the scanner.

To install software:

1. Press the Freeze button (▶|◀) to pause the system.
2. Insert the USB drive containing the software upgrade into one of the USB connectors located on the rear of the Site~Rite* 6 Ultrasound System scanner.
3. Wait until the storage device icon is illuminated before proceeding.
4. Simultaneously press and hold the Gain buttons (▲,▼) until the configuration screen appears.
5. When the configuration screen appears, simultaneously press and hold the Depth button (**cm**) and Depth Marker button (**/:**) until the software installation process begins.

   Note: The Site~Rite* 6 Ultrasound System will automatically upload the software from the attached USB drive.

   Note: The screen may appear blank and/or inactive during part of the software installation process.
6. When the system displays a message that the software update is successful, power off the Site~Rite* 6 Ultrasound System scanner.
7. Disconnect the USB drive.
8. Power on the Site~Rite* 6 Ultrasound System scanner.
9. Verify that the correct software version appears on the upper left hand corner of the screen.
10. Resume normal operation.

9 Calibrating the Rechargeable Batteries

The Site~Rite* 6 Ultrasound System batteries may occasionally require calibration to ensure the battery power meter is accurate. The following icon indicates that the Site~Rite* 6 Ultrasound System rechargeable batteries require calibration.

To calibrate the Site~Rite* 6 Ultrasound System Rechargeable Batteries:

1. Disconnect the Site~Rite* 6 Ultrasound System from A/C power.
2. Power on the Site~Rite* 6 Ultrasound System scanner and operate on battery power until the system powers off.
3. Connect the Site~Rite* 6 Ultrasound System to A/C power to recharge the batteries.

   Note: At least five hours of charge time is recommended to fully charge the Site~Rite* 6 Ultrasound System batteries.
4. Disconnect the Site~Rite* 6 Ultrasound System from A/C power.
5. Power on the Site~Rite* 6 Ultrasound System and operate on battery power until the system powers off.

   Note: The batteries are now calibrated.
6. Connect the Site~Rite* 6 Ultrasound System to A/C power to recharge the batteries and continue normal use.

10 Warranty

Bard Access Systems warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one year from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard Access Systems for repair or replacement at Bard Access Systems' option. All returns must be authorized in advance in accordance with Bard Access Systems' returned goods policy found in its then current price list. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. This warranty does not cover damages resulting from misuse, abuse, modification, alteration of this product or repair by anyone other than a Bard Access Systems representative.

The following actions void the warranty of the Site~Rite* 6 Ultrasound System:

- Opening or servicing the scanner or the probe housing by anyone other than Bard Access Systems authorized service personnel.
- Removal of system labels by anyone other than Bard Access Systems authorized service personnel.
- Opening or servicing the base power unit or the A/C adapter by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite* 6 Ultrasound System scanner to any power source other than the Site~Rite* 6 Ultrasound System A/C adapter and/or base power unit.
- Connecting the Site~Rite* 6 Ultrasound System to any unauthorized accessory.

THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT WILL BARD ACCESS SYSTEMS BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

11 Service and Repair

There is no periodic or preventive maintenance required for the Site~Rite* 6 Ultrasound System, probe or approved accessories.

For serving information or to return your Site~Rite* 6 Ultrasound System for repair, please contact Bard Access Systems Technical / Clinical Support at (800) 443-3385.

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite* 6 Ultrasound System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.

Warning: Opening or servicing the scanner, probe, base power unit, or A/C adapter by anyone other than Bard Access Systems authorized service personnel will void the warranty and may result in injury or equipment damage.

12 Technical Specifications

12.1 Operating and Storage Conditions

Operating Temperature: 59°F to 100°F (15°C to 38°C)

Storage Temperature: 50°F to 100°F (10°C to 38°C)

Operating Humidity: 5% to 85% Relative Humidity (non-condensing)

Storage Humidity (packaged): 5% to 95% Relative Humidity (non-condensing)

Storage Humidity (unpackaged): 5% to 85% Relative Humidity (non-condensing)

12.2 Scanner Specifications

Dimensions:	12" W x 13" H x 5" D
Weight:	10 lbs.
Power Sources:	A/C adapter, Internal and External DC Battery Pack
Power Consumption:	84 Watts Maximum
Monitor Size:	12.1” diagonal
IEC 60601-1:	Class I, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, Not protected against ingress of water.

12.3 Probe Acoustic Output Specifications

REF Number	Operating Mode	$I_{spta.X}$ (X denotes statistically determined maximum)	FDA $I_{spta.3}$ Published Values	MI X (X denotes statistically determined maximum)	FDA MI Published Values
9770001	B	49.003 mW/cm^2	Peripheral Vessel < 720 mW/cm^2 Cardiac < 430 mW/cm^2 Fetal Imaging & Other** < 94 mW/cm^2	.885	Peripheral Vessel < 1.9 Cardiac < 1.9 Fetal Imaging & Other** < 1.9
9772002	B	24.5 mW/cm^2	Peripheral Vessel < 720 mW/cm^2 Cardiac < 430 mW/cm^2 Fetal Imaging & Other** < 94 mW/cm^2	.993	Peripheral Vessel < 1.9 Cardiac < 1.9 Fetal Imaging & Other** < 1.9

**Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic.

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 and UD-3, and following the calibration procedures given in Appendices B, C, D and E of the 1985 FDA 510(k) Guide, and Part A, Sections III-IV, and Appendices A, B, C and D of the 1989 FDA 510(k) Guide, and the Track 1 and Track 3 reporting requirements of the September 30, 1997 Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If however a certain threshold has been passed, biological effects may occur. While the Site~Rite* 6 Ultrasound System acoustic output parameters fall well below all FDA thresholds for adverse biological effects, any given ultrasound procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

12.4 Probe Specifications

L-VA : Linear Vascular Access Probe

Frequency: 5 - 10 MHz

Elevation Focus: 1.8 cm

Maximum Scan Depth: 6.0 cm

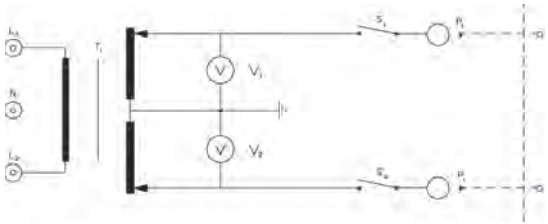
Scan Width: 1.9 cm

Lateral Foci:

Image Depth	Focal Depth
1.5 cm	0.6 cm
3.0 cm	1.5 cm
4.5 cm	3.0 cm
6.0 cm	5.0 cm

12.5 Power Supply Specifications

Note: For 240 V applications use only center tapped 240 VAC single phase power as shown below.



A/C Adapter Specifications

Input Voltage: 100-240 VAC, 50/60 Hz
Input Current (Max): 2 Amps

Output Voltage: 15 VDC
Output Current (Max): 6 Amps

Internal Battery Pack Specifications

Battery Chemistry:	Lithium Ion	**Output Current (Max):**	6 Amps
Nominal Output Voltage:	10.8 VDC	**Output Power (Full Charge):**	52 Wh

Base Power Unit Specifications (All base power units except **9760035**)

Input Voltage:	15 VDC	**Battery Output Current (Max):**	6 Amps
Input Current (Max):	6 Amps	**Battery Chemistry:**	Lithium Ion
Nominal Battery Output Voltage:	10.8 VDC	**Output Power (Full Charge):**	95 Wh

Base Power Unit Specifications (Base power unit part number **9760035**)

Input Voltage:	100-240 VAC, 50/60 Hz	**Nominal Battery Output Voltage:**	10.8 VDC
Input Current (Max):	1.7 Amps	**Output Power (Full Charge):**	95 Wh
A/C Adapter Output Voltage:	15 VDC	**Battery Output Current (Max):**	6 Amps
A/C Adapter Output Current:	7 Amps	**Battery Chemistry:**	Lithium Ion

Run and Change Times

System Without Base Power Unit:	**Run TIme:**	1 Hour
	Charge TIme:	2 Hours
System With Base Power Unit:	**Run TIme:**	3 Hours
	Charge TIme:	4 Hours

13 Standards Information

The Site~Rite* 6 Ultrasound System is designed to comply with applicable sections of the following International Standards:

- UL 60601-1: 2003, Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA - C22.2 No. 601.1-M90, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1:1988, Medical Electrical Equipment - Part 1: General Requirements for Safety
- EN 60601-1:1990, Includes Amendments A1:1993, A11:1993, A12:1993, A2:1995 and A13:1996, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-1: 2000, Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: 2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: 2004, Medical Electrical Equipment - Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 60601-1-4: 2000, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
- NEMA UD-2: 2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3: 2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- EN 55011: 1998, Group 1, Class A - Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment - Radio Disturbance Characteristics-Limits and Methods of Measurement

14 Disposal Information

To return the Site~Rite* 6 Ultrasound System for end of life recycling, please contact your nearest Bard sales or distributor office in the country of purchase.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

15 EMC Tables

Guidance and Manufacturer's Declaration – Emissions		
The Site~Rite* 6 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite* 6 Ultrasound System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The Site-Rite* 6 Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Site-Rite* 6 Ultrasound System is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The Site~Rite* 6 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite* 6 Ultrasound System should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV Input/ Output Lines	±2kV Mains ±1kV Input/ Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Site~Rite* 6 Ultrasound System requires continued operation during power mains interruptions, it is recommended that the Site~Rite* 6 Ultrasound System be powered from an uninterruptible power supply or battery.
Power Frquency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Emissions			
The Site~Rite* 6 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite* 6 Ultrasound System should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Enviroment – Guidance**
Conducted RF EN/IEC 61000-4-6 Radiated RF EN/IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile communications equipment should be separated from the Site~Rite* 6 Ultrasound System by no less than the distances calculated/ listed below: D = 1.2 (√ P) D = 1.2 (√ P) 80 to 800 MHz D = 2.3 (√ P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels. Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separations Distances between portable and mobile RF Communications equipment and the Site~Rite* 6 Ultrasound System			
The Site~Rite* 6 Ultrasound System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Site-Rite* 6 Ultrasound System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Site~Rite* 6 Ultrasound System as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz D = 1.2(√ P)	Separation (m) 80 kHz to 800 MHz D = 1.2(√ P)	Separation (m) 800 MHz to 2.5 GHz D = 2.3(√ P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Site~Rite® 6 Ultrasound System Manufactured by:

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116
U.S.A.

(801) 522-5000
Customer Service: (800) 545-0890
Technical/Clinical Support: (800) 443-3385

www.bardaccess.com

Site~Rite® Needle Guides Distributed by:

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605 North 5600 West
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(801) 522-5000
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www.bardaccess.com

SITE~RITE 6
ULTRASOUND SYSTEM

INSTRUCTIONS FOR USE

BARD

Site~Rite* 6 Ultrasound System
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An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: July, 2009

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